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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,925	01/29/2002	Kevin R. Heath	BSI-491US	9741

7590 04/13/2006
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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/059,925

Applicant(s)

HEATH ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-11, 13-38 and 44-65 is/are pending in the application.
- 4a) Of the above claim(s) 26-38 and 44-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-11, 13-25, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 February 2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 13, 18-22, 25, and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,509,897 to Twardowski et al.

In the specification and figures, Twardowski discloses the apparatus as claimed by applicant. In particular, Twardowski discloses a catheter 10 with a distal end (generally at 24) and a proximal end (generally at 11) (see column 6, lines 1-30, FIG 1). The catheter 10 comprises an elongated tube that is defined by a sidewall (not labeled) and a septum 22 that creates two lumens 18 and 20 (see FIG 2) and terminates in openings 24, 26 at the distal end of the catheter. The distal portion of the catheter is

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spirally formed into a helical or corkscrew pattern (see column 6, lines 15-30, FIG 1). A first lumen 20 extends to the end of the catheter 10 terminating in port or opening 24, while second lumen 18 terminates in a second port 26 that is spaced proximal to port 24 (see FIG 1). The openings or ports 24, 26 are coincident, or in line with the corkscrew shape of the catheter.

With regard to claim 13, Twardowski illustrates that the distal end of the catheter is located centrally within the axis of the corkscrew (see FIG 1).

With regard to claims 18-22, Twardowski discloses that the catheter may withdraw and perfuse blood in a hemodialysis operation (see columns 1-2). Twardowski further discloses that his device may be made of a flexible plastic material such as polyurethane, which is a thermoplastic elastomer (see column 6, lines 6-8).

Claim 25 sets forth that the claimed catheter is a "tunneling catheter." Such a limitation is held to be a recitation of the intended use of the device, since applicant sets forth no alternate definition of "tunneling" in the specification. There appears to be no structural difference between the catheter disclosed by Twardowski and applicant's claimed "tunneling catheter." Twardowski's catheter is capable of performing as the claimed tunneling catheter, and therefore anticipates applicant's claim.

With regard to claims 64 and 65, Twardowski discloses that the first and second lumens have openings approximately 0.5-3.0 cm from one another.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,509,897 to Twardoski, as applied above.

In the specification and figures, Twardowski discloses the apparatus substantially as claimed by applicant, with the exception of a single lumen catheter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to remove the second lumen disclosed by Twardoski to provide an infusion catheter, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. See MPEP § 2144.04. With regard to the diameter of the corkscrew section, Twardowski discloses that the helical shaped portion is of a diameter slightly larger than the catheter diameter and illustrates that the open end of the catheter is located centrally within the axis of the corkscrew (see column 6, lines 15-28, FIG 1).

6. Claims 2, 3, 5, 7, 9-11, 16, rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,509,897 to Twardoski, as applied above, in view of US 4,795,439 to Guest.

In the specification and figures, Twardowski discloses the apparatus substantially as claimed by applicant, with the exception of sidewall openings, multiple septums, and a helical sidewall opening and lumen pattern. Guest discloses a catheter 30 with a proximal and distal end and an exterior sidewall 32 with interior sidewalls, or septums, 34, 26, and 38 that define lumens 40, 42, 44. The catheter further comprises radial side holes 46 that are disposed along the lumens, which are twisted to form a helical lumen and sidewall opening pattern along the length of the catheter (see column 2, lines 14-43, FIG 2). The twisted shape and sidewall openings are configured to prevent total occlusion of a lumen if the side of the catheter comes into contact with a vessel wall (see column 1, lines 25-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a third lumen and a helical patterning of the lumens and sidewall openings to the catheter disclosed by Twardowski to prevent occlusion of the catheter, as taught by Guest.

With regard to claim 3, Twardowski discloses that the inflow bore opening is directed radially inwardly—toward the outflow lumen and away from the vessel wall (see column 2, lines 37-40, column 4, lines 40-45). In particular, it appears that opening 26 is facing generally inwardly, away from the outer periphery, or diameter of the corkscrew pattern (see FIGS 1, 3).

With regard to claims 10-11, Guest discloses that the third lumen allows for administration of medication to a patient simultaneously with a blood withdrawal and return operation. Therefore, it would have been obvious to add additional septums and

lumens as disclosed by Guest to the catheter disclosed by Twardowski, to allow for medication delivery, as taught by Guest.

7. Claims 4, 14-15, 17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,509,897 to Twardoski, as applied above, in view of 4,694,838 to Wijayarthna et al.

In the specification and figures, Twardowski discloses the apparatus substantially as claimed by applicant, with the exception of the diameter of the tube and the corkscrew portion, and the angle of termination of the helical portion. Twardowski specifically discloses that the dimensions of the catheters are chosen to match the vein in which each catheter is implanted (See column 4, lines 48-57). Wijayarthna discloses a coiled catheter for deployment in a patient's cardiovascular system that may comprise a tube diameter of 0.132-0.33 cm and a spiral diameter of 0.5-4 cm (see column 5, lines 25-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was claimed to adjust the size of the catheter disclosed by Twardowski to the dimensions disclosed by Wijayarthna, since Twardowski teaches that such modifications allow the catheter to be sized to fit the patient.

With regard to the terminal position of the corkscrew pattern, examiner has interpreted "circumferentially," and "tangentially" to mean a terminal end as illustrated in FIG 2B of applicant's specification, since applicant has not shown how a circumferential and a tangential distal end are different. Wijayarthna discloses an illustrates a loop catheter wherein the loop portion terminates with the catheter pointed tangentially (see FIG 9) in order to maintain alignment of the catheter when deployed in the aorta (see

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column 4, lines 13-16). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter disclosed by Twardoski with a tangential terminus, in order to prevent migration of the catheter when deployed in the vasculature, as taught by Wijayarthna.

With regard to applicant's recitation of the angle of the holes to the rest of the catheter (see claim 17), Wijayarthna discloses that the angle of the sidewall openings 24, 26, in the catheter are selected to correspond with the angle of blood flow through the vasculature where the catheter is deployed (see column 6, lines 10-30). Therefore, it would have been obvious to place sidewall holes in the catheter disclosed by Twardowski at various angles to the sidewall and septum of the Twardowski catheter, as disclosed by Wijayarthana, in order to maximize the efficiency of the blood flow through the catheter when it is deployed in the patient's vasculature, as taught by Wijayarthna.

With regard to claim 23, Wijayarthna discloses that the catheter may comprise a braided catheter tubing selected to give the catheter the desired torque and strength necessary to push and rotate the catheter into position (see column 5, lines 10-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a braided architecture as disclosed by Wijayarthna to the catheter disclosed by Twardowski in order to provide structural strength to the catheter, as taught by Wijayarthna.

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8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,509,897 to Twardoski in view of US 4,795,439 to Guest, as applied above, further in view of 4,694,838 to Wijayarthna et al.

In the specification and figures, Twardowski and Guest disclose the apparatus substantially as claimed by applicant, with the exception of the angle of the sidewall openings in relation to the septum of the catheter. Wijayarthna discloses that the angle of the sidewall openings 24, 26, in the catheter are selected to correspond with the angle of blood flow through the vasculature where the catheter is deployed (see column 6, lines 10-30). Therefore, it would have been obvious to place sidewall holes in the catheter disclosed by Twardowski at various angles to the sidewall and septum of the Twardowski catheter, as disclosed by Wijayarthana, in order to maximize the efficiency of the blood flow through the catheter when it is deployed in the patient's vasculature, as taught by Wijayarthna.

Response to Arguments

9. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.


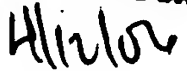
Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PATRICIA BIANCO
PRIMARY EXAMINER



Leslie R. Deak
Patent Examiner
Art Unit 3761
11 April 2006